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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,178

09/29/2005

Johannes Abraham Hollander

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10/23/2006

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EXAMINER

UNDERDAHL, THANE E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/551,178

Applicant(s)

HOLLANDER ET AL.

Examiner

Thane Underdahl

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/05/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Objection to the Specification

The examiner objects to the large blank space on page 6 of the specification. Please make the appropriate corrections.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention..

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are incomplete in the absence of a recovery step for the product produced. While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the **complete** process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Also claim 5 uses the term subfeed. It is unclear how this term limits the claim since the term "feed" in the claims already contains a combination of both carbon and nitrogen containing nutrients. It appears the applicant intends to separate the carbon and nitrogen nutrients into different subfeed lines, however there is still the possibility in

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the claim that the subfeed can contain both nutrients and as such is the same as the "feed" line thus not further limiting. Clarification is required.

Also claim 8 limits the bacteria are of the family of *Actinomycetes*. However *Actinomycetes* is a phylum not a family in the scientific classification of organisms.

Also claim 11 uses the phrase "carbon containing nutrient is for more than 50% soybean oil and the nitrogen containing nutrient is for more than 50% ammonia". This phrase is unclear because the nutrient is for the bacteria in the dependant claim 1 not for soybean oil and ammonia. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. (U.S. Patent 5,182,207, 1993) as supported by Wythes et al. (Australian J. of Experimental Ag. and Animal Husbandry, 1978).

These claims are drawn to a fermentation process for the production of a desired compound by cultivating filamentous bacteria from genus *Streptomyces* using a medium that contains nitrogen containing and carbon containing nutrients in low concentrations. Low concentrations are further defined in claims 2 and 3 as less than 0.5 g/L of nitrogen nutrient and 5 g/L carbon nutrient. The nutrients are fed into the fermentation

process. The oxygen is maintained in the process between 20 and 70% of air saturation or 30-60 % of air saturation.

Ward et al. teach strains of *Streptomyces Thermoachaensis* (from the phylum of *Actinomycetes*) that are cultured in media containing a carbon containing nutrient in the amount of 0.5 to 10 % by weight of the fermentation medium (col 10, line 18) and a nitrogen containing nutrient molasses (col 10, line 28). Molasses is included as the nitrogen source of Medium B (col 13, line 3) in a concentration of 1.5 g/L. However the amount of Nitrogen available in molasses is 0.9 % of dry molasses (as supported by Wythes et al., see Abstract). 0.9 % of 1.5 g of molasses in 1 L of medium is 0.135g which inherently meets the limitation of claim 2.

Ward et al. transfers a portion of their medium inoculated with *Streptomyces* into a 700L fermentor that is fed with additional carbon and nitrogen nutrient sources for continued fermentation (col 15, Example 5). The fermentation processes were carried out at oxygen levels greater than 30% of air saturation (col 15, line 68) and greater than 20% of air saturation (col 16, line 17).

Therefore the reference anticipates claims 1-9.

Claims 1 and 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisenschink et al. (U.S. Patent 5,902,579, page 1999).

These claims are drawn to a fermentation process for the production of a desired compound by cultivating filamentous bacteria from genus *Streptomyces* using a medium that contains nitrogen containing and carbon containing nutrients in low concentrations.

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Low concentrations of carbon sources are further specified in claim 3 as less than 5 g/L carbon nutrient. The nutrients are fed into the fermentation process. The oxygen is maintained in the process between 20 and 70% of air saturation or more specifically 30-60 % of air saturation. The desired compound is more specifically defined in claim 10 as natamycin (also known as pimaricin). Also the bacteria to produce natamycin is more specifically defined as *S. natalensis* or *S. gilvospereus*.

Eisenschink et al. teach a fermentation process using either *Streptomyces gilvoporeus* or *Streptomyces natalensis* both from the phylum of *Actinomycetes* to prepare natamycin (col 2, lines 11-20). The medium to ferment these bacteria contains 2-16 g/L of a protein nitrogen source about 5 g/L of a carbon source (col 3, lines 10-15). After an initial fermentation period the *Streptomyces* containing medium is fed (col 3, lines 23-26) into a larger fermentation medium containing more carbon and nitrogen nutrients which "are initially added to the fermentation medium and addition continued after the fermentation has begun" (col 4, lines, 10-15). The fermentation process is carried out at an oxygen level of 50% of air saturation.

Therefore the reference anticipates claims 1 and 3-10.

Claims 1, 2, 4, 5, 8, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Junker et al. (Biotech. And Bioeng., 1998).

These claims are drawn to a fermentation process for the production of a desired compound by cultivating filamentous bacteria from genus *Streptomyces* using a medium that contains nitrogen containing and carbon containing nutrients in low concentrations.

The nutrients are fed into the fermentation process. The source of the carbon and nitrogen containing nutrients are further defined in claim 11 as from soybean oil and ammonia respectively.

Junker et al. teach a fermentation process to produce valine (a desired compound) using *Streptomyces hydroscopicus* (from the phylum of *Actinomycetes*) (see Abstract). The fermentation medium contained soybean oil and ammonium sulfate (sulfate salt of ammonia) (see Abstract). The amount of ammonium sulfate can range from 0-18 g/L (page 582, 1st full paragraph, and page 587, Figure 9). The ammonium sulfate and soybean oil are fed into the reactor during the fermentation (page 587, Use of Mid-Cycle Ammonium Sulfate and Soybean Oil Shots in Ammonium Sulfate-Based GYG5 Medium).

Therefore the reference anticipates claims 1, 2, 4, 5, 8, 9 and 11.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

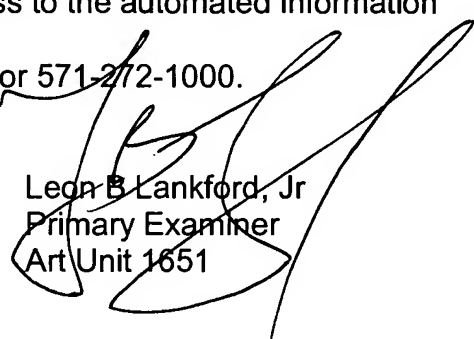
Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached on 8:00 to 17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651



Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651